GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

STARRED QUESTION NO:548
ANSWERED ON:14.05.2007
REGULATORY AUTHORITY FOR PHARMA INDUSTRY
Rao Shri Kavuru Samba Siva

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the nature and number of disputes between the major pharma companies and the Government noticed during each of the last three years;

(b) the status of new pricing mechanism as major pharma companies are opposing the reduction in prices of drugs;

(c) whether the Government proposes to set up a Regulatory Authority for the Pharma Industry to investigate into cases of overpricing and finalize the settlement of dues and to punish the companies that violate the existing pricing policy on drugs;and:

(d) if so, the details thereof?

Answer

THE MINISTER OF CHEMICALS AND FERTILIZERS & MINISTER OF STEEL (SHRI RAM VILAS PASWAN)

(a)to(d) : A Statement is laid on the Table of the House.

STATEMENT REFERRED IN REPLY TO PARTS (a) to (d) OF THE LOK SABHA STARRED QUESTION NO.548 FOR ANSWER ON 14-5-2007 ON THE SUBJECT OF REGULATORY AUTHORITY FOR PHARMA INDUSTRY.

(a) to (d): The prices of 74 bulk drugs specified in the First Schedule of the Drugs (Prices Control) Order, 1995 (DPCO 1995) and the formulations based thereon are controlled in accordance with the provisions of the DPCO 1995 by the National Pharmaceutical Pricing Authority (NPPA).NPPA regularly takes action against pharma companies who do not implement the prices fixed/notified by NPPA under the provisions of DPCO 1995 and this is a continuous and on going process.Disputes between pharma companies and Government arise when a Show Cause Notice issued to a company for recovery of overcharged amount is contested by it in a court of law. During the last 3 years about 40 disputes/litigations have arisen between major pharma companies and the Government on this issue.
Keeping in view the directions of the Supreme Court in SLP No. 3668/2003 and in line with the declared objective of the Government in the National Common Minimum Programme to make available life saving and essential drugs at reasonable prices to the poor, the draft National Pharmaceuticals Policy-2006 proposes, inter alia, that the basket for price control would be the essential medicines as contained in the National List of Essential Medicines,2003.
Draft National Pharmaceutical Policy was considered by the Cabinet at its meeting held on 11.1.2007. The Cabinet has referred the Policy to Group of Ministers (GOM). The First meeting of the GOM was held on 10.4.2007. No time frame has been set for finalizing the National Pharmaceuticals Policy.
At present NPPA is the regulatory authority to investigate cases of over pricing under the provisions of DPCO 1995 issued under the Essential Commodities Act, 1955 (EC Act, 1955).In the EC Act, there is no provision for settlement of dues.